

WHAT IS CLAIMED IS:

1. A method for determining the amount of Lp(a) in a sample comprising the steps of:
 - (a) contacting said sample and an Lp(a) specific binding agent coupled to a solid support wherein said Lp(a) specific binding agent is a monoclonal antibody or
 - 5 fragment thereof that specifically binds to kringle 5 of apo(a) for a time and under conditions to form binding agent-Lp(a) complexes; and
 - (b) determining the amount of Lp(a) bound to said binding agent-Lp(a) complexes.
2. The method of Claim 1 wherein said monoclonal antibody binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LDL, VLDL, IDL and HDL, at less than 2% of Lp(a) binding.
3. The method of Claim 1 wherein said monoclonal antibody is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.
4. The method of Claim 2 wherein the solid support is selected from the group consisting of nitrocellulose, latex, nylon, polystyrene, beads, particles, magnetic particles, and glass fiber.
5. The method of Claim 1 further comprising the step of separating said solid support from said sample before determining the amount of Lp(a) bound to said binding agent-Lp(a) complexes.
6. The method of Claim 1 further comprising contacting an indicator reagent with said sample and said Lp(a) specific binding agent prior to step (b).

7. The method of Claim 6 wherein said Lp(a) specific binding agent binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LDL, VLDL, IDL and HDL at less than 2% of Lp(a) binding.

8. The method of Claim 6 wherein said indicator reagent is selected from the group consisting of K4 specific monoclonal antibody, K4 polyclonal antibody, K4/K5 monoclonal antibody, K4/K5 polyclonal antibody and fragments of each.

9. The method of Claim 6 further comprising the step of separating said solid support from said sample before determining the amount of Lp(a) bound to said binding agent-Lp(a) complexes.

10. The method of Claim 6 wherein said Lp(a) specific binding agent is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

11. A method for determining the amount of Lp(a) in a sample comprising the steps of:

(a) contacting said sample, an indicator reagent, and a capture reagent bound to a solid support wherein said indicator reagent is a labeled monoclonal antibody or fragment thereof that specifically binds to kringle 5 of apo(a) for a time and under conditions to form capture reagent-Lp(a)-indicator reagent complexes; and

(b) determining the amount of Lp(a) bound to said binding agent-Lp(a) complexes.

12. The method of Claim 11 wherein said indicator reagent binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LDL, VLDL, IDL and HDL at less than 2% of Lp(a) binding.

13. The method of Claim 11 wherein said capture reagent is selected from the group consisting of K4 specific monoclonal antibody or a fragment thereof, K4 polyclonal antibody, K4/K5 monoclonal antibody, K4/K5 polyclonal antibody and fragments of each.

14. The method of Claim 11 further comprising the step of separating said solid support from said sample before determining the amount of Lp(a) bound to said binding agent-Lp(a) complexes.

15. The method of Claim 11 wherein said indicator reagent is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

16. A method for determining the amount of Lp(a) in a sample comprising the steps of:

(a) contacting said sample, an Lp(a) specific binding agent wherein said Lp(a) specific binding agent is conjugated to a first charged substance, and an indicator reagent wherein said indicator reagent is monoclonal antibody or fragment thereof that specifically binds to kringle 5 of apo(a) for a time and under conditions to form binding agent-Lp(a)-indicator complexes;

(c) contacting an insoluble solid phase material which is oppositely charged with respect to said first charged substance, such that said solid phase material attracts and attaches to said first charged substance; and

(d) determining the amount of Lp(a) bound to said binding agent-Lp(a)-indicator reagent complexes.

17. The method of Claim 16 wherein said monoclonal antibody is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

18. The method of Claim 16 wherein said first charged substance is an anionic or cationic monomer or polymer.

19. The method of Claim 16 wherein said indicator reagent binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LDL, VLDL, IDL and HDL at less than 2% of Lp(a) binding.

20. A method for determining the amount of Lp(a) in a sample comprising the steps of:

(a) contacting said sample with an indicator reagent wherein said indicator reagent is a monoclonal antibody or fragment thereof that specifically binds to kringle 5 of apo(a) and with a solid support coated with Lp(a) for a time and under conditions to permit
5 binding of said indicator reagent with said Lp(a) in said test sample and with said bound Lp(a); and

(b) determining said amount of Lp(a) in said test sample by detecting the reduction in binding of said indicator reagent to said solid support as compared to the signal generated from a negative sample to indicate the presence of Lp(a) in said test sample.

21. The method of Claim 20 wherein said monoclonal antibody binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LpDL, VLDL, IDL, and HDL at less than 2% of Lp(a) binding.

22. The method of Claim 20 wherein said monoclonal antibody is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

23. The method of Claim 20 wherein at each occurrence therein, said indicator reagent is replaced by labeled Lp(a) and said bound-Lp(a) is replaced by bound monoclonal antibody or a fragment thereof that specifically binds to kringle 5 of apo(a).

24. The method of Claim 23 wherein said monoclonal antibody binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LpDL, VLDL, IDL, and HDL at less than 2% of Lp(a) binding.

25. The method of Claim 23 wherein said monoclonal antibody is selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

26. The method of Claim 22 wherein at each occurrence therein, said labeled Lp(a) is replaced by labeled kringle 5 of apo(a).

27. A method for determining the amount of cholesterol associated with Lp(a) in a sample comprising:

- (a) contacting a sample and a monoclonal antibody or fragment thereof that specifically binds to kringle 5 of apo(a) wherein said antibody is coupled to a solid support;
- (b) separating said solid support from said sample; and
- (c) determining said amount of cholesterol bound to said solid support.

28. A monoclonal antibody specific for Lp(a) wherein said antibody binds to substantially all Lp(a) via kringle 5, to plasminogen at less than 1% of Lp(a) binding and to LDL, VLDL, HDL and IDL at less than 2% of Lp(a) binding.

29. The antibody of Claim 28 which is an IgG isotype.

30. The antibody of Claim 29 selected from the group consisting of 1-532-266, 1-390-191, 1-458-165 and 1-892-230.

31. The antibody of Claim 30 which is 1-892-230.

32. The antibody of Claim 31 which is an IgM isotype.

33. The antibody of Claim 32 selected from the group consisting of 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

34. A monoclonal antibody specific for Lp(a) prepared by a method comprising the steps of:

- (a) immunizing a mouse or a rat with kringle 5 of apo(a) or a fragment thereof;
- 5 (b) making a suspension of mouse or rat spleen cells;
- (c) fusing said spleen cells with mouse or rat myeloma cells in the presence of a fusion promoter;
- (d) culturing said fused cells;
- (e) determining the presence of anti-Lp(a) antibody in the culture media;
- 10 (f) cloning a hybridoma producing antibody that binds to substantially all Lp(a), to plasminogen at less than 1% of Lp(a) binding and to other lipoproteins, such as, LDL, VLDL, IDL and HDL at less than 2% of Lp(a) binding; and
- (g) obtaining said antibody from said hybridoma.

35. A hybridoma cell line that secretes a monoclonal antibody that binds to substantially all Lp(a), to plasminogen at less than 1% of Lp(a) binding and to other lipoproteins, such as, LDL, VLDL, IDL and HDL at less than 2% of Lp(a) binding.

36. A hybridoma cell line that secretes a monoclonal antibody selected from the group consisting of 1-532-266, 1-390-191, 1-458-165, 1-892-230, 1-292-189, 1-431-378, 1-746-183, and 1-546-264.

37. A test kit for the detection and quantification of Lp(a) in a plasma sample, comprising a reagent which specifically binds to kringle 5 of apo(a).

38. The test kit of Claim 37 wherein said reagent is labeled.